K101834 1/2

5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

SEP 3 2010

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Jizhong Jin
Regulatory Affairs Specialist
Phone Number: (651) 733-6655
FAX Number: (651) 737-5320

Date of Summary: June 30, 2010

Device Name and Classification:

Common or Usual Name: Telemedicine Module

Proprietary Name: 3M™ Littmann® Scope-to-Scope Software System

Classification Name: Transmitters and receivers, physiological signal, radiofrequency (21 CFR § 870.2910)

Performance Standards: N/A

Predicate Device:

CareTone® Telephonic Stethoscope (K973873 American TeleCare's Digital Personal Telemedicine Module)

Description of Device:

The 3M™ Littmann® Scope-to-Scope Software System consists of software on a CD working with two 3M Littmann® Model 3200 Electronic Stethoscopes (cleared under K083903), such that when the software program is installed onto a PC, the software provides and controls real time data transfer of body sounds between two 3M Littmann® Model 3200 Electronic Stethoscopes over a data network. The sound captured by the stethoscope at the Patient site can be heard equivalently at both the Patient and Consulting sites through the Model 3200 headsets. The Scope-to-Scope Software System can be used on any person undergoing a physical assessment, thereby enabling health care professionals in remote clinics to obtain a second opinion from clinicians in a different location.

Both sites' Model 3200 electronic stethoscopes are connected to Microsoft Windows-based PC's via a Bluetooth wireless link. The two PC's are then connected to each other over a TCP/IP data network. The software allows for the Consulting site to control the Patient site's filter settings remotely when connected. The software also provides for the ability to facilitate verbal communication using the stethoscope's 'talk-through' feature that utilizes an expanded frequency range to better capture voice audio. This allows the Consultant to provide verbal cues and/or directions to the Patient site.

Indications for Use:

The 3M™ Littmann® Scope-to-Scope software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this 510(k) submission shows that the 3M™ Littmann® Scope-to-Scope Software System is substantially equivalent to the predicate device CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module) cleared under K973873 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 3 2010

3M Company
3M Health Care
c/o Ms. Jizhong Jin
3M Health Center, Bldg. 275-05-W-06
St. Paul, MN 55144-1000

Re: K101834
Trade/Device Name: 3M Littman Scope to Scope Software System (TS1000P, RS1000C, 3200TMC)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: June 30, 2010
Received: July 1, 2010

Dear Ms. Jin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

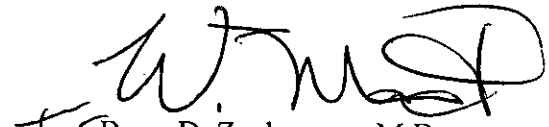
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101834

4.0 Indications for Use Statement

SEP 3 2010

Indications for Use

510(k) Number (if known):

Device Name: 3M™ Littmann® Scope-to-Scope Software System

Indications For Use:

The 3M™ Littmann® Scope-to-Scope Software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101834

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